OCT - 7 2003

i-STAT CORPORATION

K031813

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

The assigned 510(k) number is:

Summary prepared on: June 12, 2003

Submitted by:
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Contact:
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Establishment Registration Number: 2245578

Identification of Device:
Device Name: i-STAT Cardiac Markers Control Level 1
i-STAT Cardiac Markers Control Level 2
i-STAT Cardiac Markers Control Level 3
i-STAT Cardiac Markers Calibration Verification Control Set
Proprietary/Trade Name: i-STAT Cardiac Markers Control Level 1
i-STAT Cardiac Markers Control Level 2
i-STAT Cardiac Markers Control Level 3
i-STAT Cardiac Markers Calibration Verification Control Set
Common Name: cardiac marker controls, cardiac marker calibration verification set
Device Classification: I
Regulation Number: 21 CFR§ 862.1660
Panel: Single (Specified) Analyte Controls (Assayed and Unassayed)
Product Code: JJX

Identification of the Predicate Device:
Device Name: More Diagnostics Cardiac Markers Control

Intended Use of the Devices:

Cardiac Markers Control (Level 1, Level 2, and Level 3)
The i-STAT Cardiac Markers Controls are an assayed liquid serum used to verify the integrity of newly received i-STAT cTnI cartridges.

Cardiac Markers Calibration Verification Control Set
The i-STAT Cardiac Markers Calibration Verification Controls are an assayed liquid serum used to verify the calibration of i-STAT cTnI cartridges throughout the reportable range.

K031813

Description of the Device:
The i-STAT Cardiac Markers Controls are supplied in three levels packaged as six vials of one level per box, with each vial containing 1 mL of control material. The three levels are each comprised of a different level of cardiac Troponin I, human creatinine kinase –MB isoform CK-MB, and myoglobin (all native forms) derived from human cardiac material, prepared in human serum, and preserved with sodium azide to inhibit microbial growth. The CK-MB and myoglobin are unassayed components in these materials. Only the cardiac troponin I (cTnI) values will be provided in the value assignment sheets for these products.

The Cardiac Markers Calibration Verification Control Set is packaged as a tri-level set, comprised of two vials of each of three levels per box.

Comparison to Technological Features of the Predicate Device:
The similarities and differences between the i-STAT controls products and the More Diagnostics control products can be seen in the table below.

List of similarities and differences between the i-STAT and predicate device

Characteristics	i-STAT Cardiac Markers Control Level 1, 2, & 3 and i-STAT Cardiac Markers Calibration Verification Control Set (new device)	More Diagnostics Cardiac Markers Control (predicate device)
Similarities		
Matrix	Human Serum	Human Serum
Preservative	Sodium Azide	Sodium Azide
Form	Frozen liquid	Frozen liquid
Opened Vial Claim	4 hours when stored at 2 to 8°C	4 hours when stored at 2 to 8°C
Differences		
Analytes	CKMB (unassayed) Myoglobin (unassayed) cTroponin I (assayed)	CKMB (assayed) Myoglobin (assayed) cTroponin I (assayed)
Vial	10 mL plastic vial with dropper-top	Plastic bulb
Fill volume	1 mL	300 µL
Storage (unopened)	≤ -18°C until expiration date	-14°C to -22 °C until expiration date

Summary of Performance in Support of Substantial Equivalence:
- The within-level vial-to-vial imprecision for all three levels of the i-STAT cardiac markers controls was found to range from 1.9% to 5.7% testing three lots of each control level.
- Studies demonstrated that all three levels meet the claim of 4 hours' stability after the product has been thawed.

Conclusions:
The i-STAT Cardiac Markers Control Level 1, Level 2, and Level 3, and the i-STAT Cardiac Markers Calibration Verification Control Set are substantially equivalent to the previously cleared More Diagnostics Cardiac Markers Control as indicated by the data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 7 2003

Ms. Sue Kent
Manager, Clinical Affairs
i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520

Re: k031873
Trade/Device Name: i-STAT Cardiac Markers Control Level 1
i-STAT Cardiac Markers Control Level 2
i-STAT Cardiac Markers Control Level 3
i-STAT Cardiac Markers Calibration Verification Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: September 2, 2003
Received: September 3, 2003

Dear Ms. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

3 a. Indications for use

510(k) Number (if known): K031873

Device Names: **i-STAT Cardiac Markers Control Level 1**
i-STAT Cardiac Markers Control Level 2
i-STAT Cardiac Markers Control Level 3

The i-STAT Cardiac Markers Controls are used to verify the integrity of newly received i-STAT cTnI cartridges.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K031873

3 b. Indications for use

510(k) Number (if known): K031873

Device Name: **i-STAT Cardiac Markers Calibration Verification Control Set**

The i-STAT Cardiac Markers Calibration Verification Control Set is used to verify the accuracy of results over the measurement range of the i-STAT cTnI test.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

Carol C. Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031873